

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

DMB

Display Date	9-4-01
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Certifier	<i>R. Sedman</i>

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 3 and 4, 2001, from 8:30 a.m. to 5 p.m.

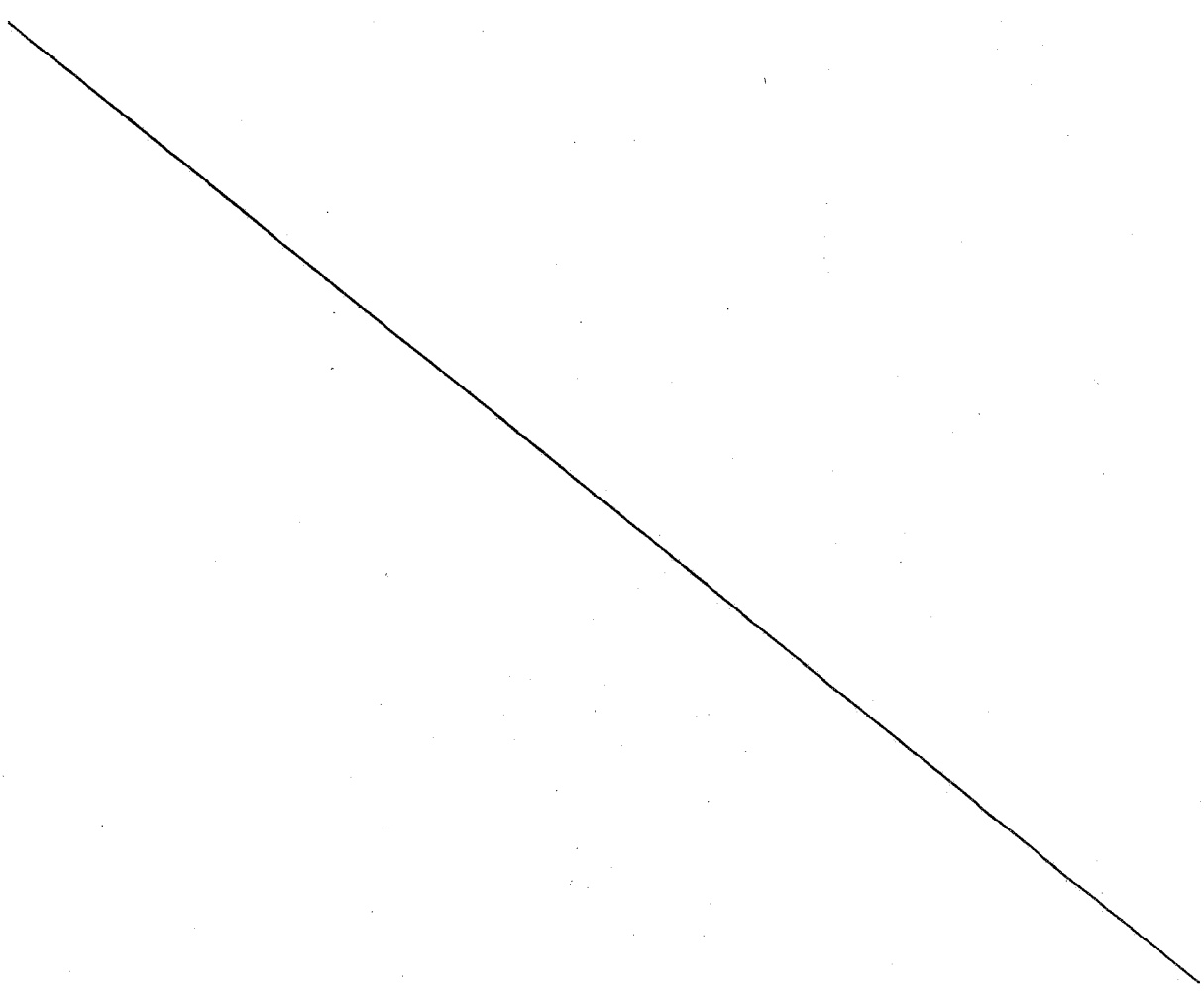
Location: The Town Center Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 3, 2001, the committee will discuss new drug application (NDA) 21-356, Viread™ (tenofovir disoproxil fumarate) Tablets, Gilead Sciences, Inc., proposed for the treatment of human immunodeficiency virus (HIV) infection. On October 4, 2001, the committee will discuss NDA 21-266, Vfend™ (voriconazole) Tablets and NDA 21-267, Vfend™ I.V. (voriconazole) for infusion, Pfizer Global Research and Development, proposed for the treatment

of invasive aspergillosis, serious *Candida* infections, infections caused by *Scedosporium* spp. and *Fusarium* spp., rare and refractory infections, and empirical treatment of febrile neutropenia.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 26, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

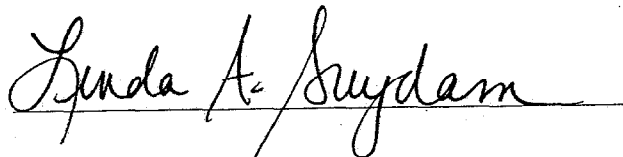


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: August 28, 2001

August 28, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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